UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

Children's Health Defense, *et al.*, Plaintiffs, v. Food & Drug Administration, *et al.*, Defendants.	Case No. 6:22-cv-00093-ADA-DTG

Defendants' Motion to Dismiss for Lack of Subject-Matter Jurisdiction and Failure to State a Claim Upon Which Relief Can Be Granted

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INTRODUCTION

In October 2021, the U.S. Food and Drug Administration ("FDA") issued an emergency use authorization for administration of the Pfizer-BioNTech COVID-19 vaccine to children aged 5 to 11 ("the Pfizer EUA"). Since then, many American parents have chosen to vaccinate their children against the virus that causes COVID-19. And many other parents have not, as they are free to decide.

Plaintiffs Deborah Else and Sacha Dietrich belong to the latter camp. But Else, Dietrich, and the advocacy group to which Else belongs—Children's Health Defense ("CHD")—are not content for American parents to make their own decisions about vaccination. Instead, Plaintiffs seek to invalidate the Pfizer EUA as it applies to all children aged 5 to 11. Their quest is legally baseless and should be dismissed.

For starters, this Court lacks subject-matter jurisdiction for two reasons. *First*, no Plaintiff has standing. Else and Dietrich lack standing because none of their children faces an imminent threat of harm from the Pfizer EUA's mere existence. Because Else lacks standing, CHD cannot establish representational standing through any identified member. And the Complaint does not plausibly show any injury to CHD itself, the prerequisite for organizational standing.

Second, even if any plaintiff possessed standing, sovereign immunity deprives this Court of jurisdiction. Both claims in the Complaint depend on the Administrative Procedure Act's ("APA") waiver of sovereign immunity. But FDA's issuance of an EUA ranks among the class of agency actions that Congress exempted from review under the APA. Not subject to the APA's waiver of sovereign immunity (or any other similar waiver), Plaintiffs' challenge cannot proceed.

Finally, even if Plaintiffs could establish this Court's subject-matter jurisdiction, they still have not plausibly alleged any claim upon which relief can be granted. Plaintiffs' APA and Declaratory Judgment Act claims are unsupported by statute or

precedent, and their factual challenges are refuted by the face of FDA's documents that are attached to or incorporated by reference in the Complaint. These claims fail as a matter of law.

BACKGROUND

I. FDA's issuance of the Pfizer EUA for children aged 5 to 11

Ordinarily, a manufacturer of a biological product, including a vaccine, may market the product "only if the FDA has licensed it" pursuant to the Public Health Service Act. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017); *see* 42 U.S.C. § 262(a), (i)(1). But in times of "an actual or potential emergency," Congress empowered the Secretary of Health and Human Services ("the Secretary") to authorize the introduction into interstate commerce of biological products (and other FDA-regulated products) "intended for use" in responding to the emergency. 21 U.S.C. § 360bbb-3(a)(1).

The Secretary first must determine that a "public health emergency . . . affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad." *Id.* § 360bbb-3(b)(1)(C). The Secretary then may declare that circumstances exist justifying the marketing of FDA-regulated products "intended for use" in responding to the emergency. *Id.* § 360bbb-3(a)(1), (b). Following those declarations, FDA may issue an EUA for a vaccine intended for use in diagnosing, treating, or preventing the disease or condition that created the emergency. *Id.* § 360bbb-3(c). Congress expressly committed all these decisions to agency discretion. *Id.* § 360bbb-3(i).

On February 4, 2020, the Secretary determined, under 21 U.S.C. § 360bbb-3(b)(1)(C), that a public health emergency existed involving the virus SARS-CoV-2, which causes COVID-19. 85 Fed. Reg. 7316, 7317 (Feb. 7, 2020). On March 27, 2020, the Secretary declared that "circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic." 85 Fed. Reg. 18,250,

18,250–51 (Apr. 1, 2020). FDA subsequently issued EUAs for COVID-19 vaccines manufactured by Pfizer-BioNTech, ModernaTX, Inc., and Janssen Biotech, Inc. *See* 86 Fed. Reg. 5200 (Jan. 19, 2021) (initial Pfizer and Moderna EUAs); 86 Fed. Reg. 28,608 (May 27, 2021) (initial Janssen EUA). Only the Pfizer EUA is relevant to this case. Ex. 1, Burk Decl. ("January Letter")[1]; *see* Compl., ECF No. 1, at ¶ 22.

On October 29, 2021, "FDA concluded that it [was] reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in individuals 5 through 11 years of age."[2] January Letter 7. The agency also concluded, "based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine" for those aged 5 through 11 years. *Id.* In reaching those conclusions, FDA reviewed extensive safety and effectiveness data, including data from a clinical trial involving "4,695 participants 5 through 11 years of age." *Id.*; *see generally* Ex. 5, EUA Mem., ECF No. 1, at 178–225. The agency also considered the vote, by the Vaccines and Related Biological Products Advisory Committee, "in agreement with" these conclusions. January Letter 7; *see* EUA Mem., ECF No. 1, at 219–20.

The Pfizer EUA requires vaccination providers to make available an approved "Fact Sheet for Recipients and Caregivers," in hardcopy or online. January Letter 14–15,

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[1] The operative EUA on the Complaint's filing date was the January 3, 2022 reissuance. Burk Decl. ¶¶ 5–6; *see Newman-Green, Inc. v. Alfonzo-Larrain*, 490 U.S. 826, 830 (1989) ("[F]ederal jurisdiction ordinarily depends on the facts as they exist when the complaint is filed."). The Court may consider the January Letter for this motion to dismiss because it is the operative agency action challenged by and discussed in the Complaint. *See, e.g.*, *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498–99 (5th Cir. 2000). Also, "judicial notice of publicly-available documents . . . produced by the FDA, which were matters of public record directly relevant to the issue at hand is appropriate." *Yosowitz v. Covidien LP*, 182 F. Supp. 3d 683, 688 (S.D. Tex. 2016) (quotation omitted); *see* Burk Decl. ¶ 6.

[2] Although the Pfizer EUA encompasses administration for all individuals aged 5 and above, *see* January Letter 10–12, only the portion related to children aged 5 through 11 is at issue here, *see, e.g.*, Compl. ¶¶ 22, 201.

18. The Fact Sheet, which is publicly available on FDA's website, informs parents and other caregivers that "there is an option to accept or refuse receiving the vaccine." Ex. 2, Burk Decl. ("Fact Sheet"), at 5. A decision "not to receive" the vaccine "will not change [the] child's standard medical care." *Id.*; *see* 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III) (among other conditions of authorization, "individuals to whom the product is administered are informed . . . of the option to accept or refuse administration of the product").

II. CHD's opposition to COVID-19 vaccines, and this lawsuit

CHD is a Georgia-based advocacy group that opposes the COVID-19 vaccines. *See* Compl. ¶ 5. In May 2021, CHD petitioned FDA to "refrain from licensing COVID-19 vaccines and to revoke EUAs for the three existing COVID-19 vaccines." *Id.* ¶ 39; *see* Ex. 2, Citizen Pet., ECF No. 1, at 64–83. Three months later, FDA provided a detailed response of more than 50 pages. *See* Compl. ¶ 40; Ex. 3, Citizen Pet. Resp., ECF No. 1, at 84–137. The agency denied CHD's petition because it lacked "facts demonstrating any reasonable grounds for the requested action." Citizen Pet. Resp., ECF No. 1, at 86.

CHD also has pursued (unsuccessfully) its objections to COVID-19 vaccines through the courts. *See Children's Health Def. v. FDA*, No. 121CV00200DCLCCHS, 2021 WL 5756085, at *1, 6 (E.D. Tenn. Nov. 30, 2021) (dismissing CHD's challenge to Pfizer's COVID-19 vaccine for lack of standing), *appeal docketed* No. 21-6203 (6th Cir. Dec. 17, 2021); *Children's Health Def. v. Rutgers State Univ. of N.J.*, No. CV2115333ZNQTJB, 2021 WL 4398743, at *1, 8 (D.N.J. Sept. 27, 2021) (denying CHD's motion for a preliminary injunction against university COVID-19 vaccination policy); *see also Aviles v. Blasio*, No. 20 CIV. 9829 (PGG), 2021 WL 796033, at *16 (S.D.N.Y. Mar. 2, 2021) (dismissing CHD, for lack of standing, from challenge to New York City school COVID-19 policy).

On January 24, 2022, CHD returned to court and, alongside Else and Dietrich, filed this suit against FDA and Robert M. Califf, M.D., Commissioner of Food and Drugs.[3] Plaintiffs challenge FDA's issuance of the Pfizer EUA for children aged 5 to 11, alleging one APA claim and another for declaratory relief. *See* Compl. ¶¶ 155–207. Defendants now move to dismiss the Complaint under Federal Rule of Civil Procedure 12(b)(1) and (b)(6) for lack of subject-matter jurisdiction and failure to state a claim upon which relief can be granted.

LEGAL STANDARD

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(1) challenges the Court's subject-matter jurisdiction, which must "be established as a threshold matter." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94–95 (1998). The Court "presume[s]" to "lack jurisdiction" unless Plaintiffs meet their "burden of establishing it." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3 (2006) (quotations omitted)); *see Brownback v. King*, 141 S. Ct. 740, 749 (2021) (plaintiff "must plausibly allege all jurisdictional elements"). If the burden is not met, the Court "must dismiss the action." Fed. R. Civ. P. 12(h)(3). "In deciding a motion to dismiss for lack of subject matter jurisdiction, a court may consider (1) the complaint alone; (2) the complaint supplemented by undisputed facts; or (3) the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." *Tenth St. Residential Ass'n v. City of Dall.*, 968 F.3d 492, 498–99 (5th Cir. 2020).

"To survive a motion to dismiss" under Rule 12(b)(6), Plaintiffs' "complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The Court need not accept as true "conclusory

[3] Dr. Califf automatically substitutes as defendant for his predecessor, Janet Woodcock, M.D., Acting Commissioner of Food and Drugs. Fed. R. Civ. P. 25(d).

statements" or "legal conclusions." *Iqbal*, 556 U.S. at 678–79. The complaint must "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged," *Iqbal*, 556 U.S. at 678, and "raise a right to relief above the speculative level," *Twombly*, 550 U.S. at 555. "[I]f as a matter of law 'it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations,' a claim must be dismissed, without regard to whether it is based on an outlandish legal theory or on a close but ultimately unavailing one." *Neitzke v. Williams*, 490 U.S. 319, 326–27 (1989) (quoting *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)).

ARGUMENT

I. Plaintiffs fail to establish this Court's subject-matter jurisdiction

Two bedrock jurisdictional precepts require the dismissal of this case. First, "[u]nder Article III, federal courts do not possess a roving commission to publicly opine on every legal question" and "do not exercise general legal oversight of the Legislative and Executive Branches." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021). Litigants "raising only a generally available grievance about government," *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 573–74 (1992)—"however sharp" their disagreement, *Hollingsworth v. Perry*, 570 U.S. 693, 704 (2013)—do not properly invoke Article III jurisdiction. Lacking any cognizable injury, Plaintiffs are not proper litigants.

Second, "[i]t is axiomatic that the United States may not be sued without its consent and that the existence of consent is a prerequisite for jurisdiction." *United States v. Mitchell*, 463 U.S. 206, 212 (1983). Accordingly, "[a]bsent a waiver, sovereign immunity shields the Federal Government and its agencies from suit." *FDIC v. Meyer*, 510 U.S. 471, 475 (1994). Plaintiffs' claims are not covered by a requisite waiver.

A. No Plaintiff has standing

The standing "doctrine limits the category of litigants empowered to maintain a lawsuit in federal court" only to those who "have (1) suffered an injury in fact, (2) that is

fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016); *see Lujan*, 504 U.S. at 560–61. This "triad of injury in fact, causation, and redressability constitutes the core of Article III's case-or-controversy requirement." *Steel Co.*, 523 U.S. at 103–04. Because "standing is not dispensed in gross," Plaintiffs "must demonstrate standing for each claim that they press and for each form of relief that they seek." *TransUnion*, 141 S. Ct. at 2208. None of the three Plaintiffs has standing.

1. With no actual or imminent injury to themselves or their children, Else and Dietrich lack standing

Beginning with the two individual plaintiffs, Else and Dietrich must establish an injury-in-fact "that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" *Spokeo*, 578 U.S. at 339 (quoting *Lujan*, 504 U.S. at 560). Else and Dietrich aver an "imminent risk of immediate harm" to their children if they were to receive the Pfizer vaccine. Compl. ¶¶ 6–7.[4] "For a threatened future injury to satisfy the imminence requirement, there must be at least a 'substantial risk' that the injury will occur." *Stringer v. Whitley*, 942 F.3d 715, 721 (5th Cir. 2019). "[A]llegations of possible future injury are not sufficient," *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013), because they are "too speculative for Article III purposes," *Stringer*, 942 F.3d at 721 (quotations omitted). That is the situation here.

Consistent with the underlying statutory authority, *see* 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III), the Pfizer EUA does not compel any individual to receive the vaccine nor any parent to consent to administration to their child, *see generally* January Letter. Rather, as the caregiver Fact Sheet expressly states, "there is an option to accept or refuse receiving the vaccine. Should you decide for your child not to receive it, it will

[4] Although the Complaint alleges "[c]hildren in Texas are being denied medical services, including transplants, without vaccination," Compl. ¶ 127, Else's and Dietrich's children are not claimed to be among them.

not change your child's standard of medical care." Fact Sheet 5. Texas law also affords Else and Dietrich the right to consent, or "not to consent," to their children's medical care, including whether to receive the Pfizer EUA vaccine. *Miller ex rel. Miller v. HCA, Inc.*, 118 S.W.3d 758, 766 (Tex. 2003); *see* Tex. Fam. Code Ann. § 151.001(6) (West). So by simply continuing to withhold consent, Else and Dietrich will prevent the future injury they fear from manifesting. In these circumstances—"an injury at some indefinite future time, and the acts necessary to make the injury happen are at least partly within the plaintiff's own control"— imminence "has been stretched beyond the breaking point." *Lujan*, 504 U.S. at 564 n.2; *see Coal. for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275, 1280 (D.C. Cir. 2012) (Kavanaugh, J.) ("In light of plaintiffs' avowed intention to refuse thimerosal-preserved vaccines, plaintiffs cannot show that they face a 'certainly impending,' or even likely, risk of future physical injury from thimerosal in vaccines.").

Dietrich nonetheless suggests a risk to her children arises from unspecified "local and school mandates" and "directives to receive the COVID-19 biologic." Compl. ¶¶ 7, 186. She correctly does not suggest that FDA could "mandate vaccines for the general public." EUA Mem., ECF No. 1, at 220. Nor could state or local authorities in Texas, where she and Else reside, Compl. ¶¶ 6–7, issue such a COVID-19 vaccine mandate. By executive order, the governor has prohibited any "entity in Texas" from "compel[ing] receipt of a COVID-19 vaccine by any individual, . . . who objects to such vaccination for any reason of personal conscience, based on a religious belief, or for medical reasons." Executive Order GA-40 (Oct. 11, 2021); *see* Tex. Gov't Code § 418.012 ("Executive orders . . . have the force and effect of law."). Given the executive order's prohibition, "[s]uch a remote possibility of harm" from hypothetical local or school vaccine mandates "fails [standing's] imminence requirement." *Tenth Street*, 968 F.3d at 501; *see id.* (no standing when city ordinance prohibited funding the feared demolition of homes).

Even if Dietrich fears a potential rescission of the executive order and imposition of a state vaccination mandate for children aged 5 through 11, such "unadorned

speculation will not suffice to invoke the federal judicial power." *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 44 (1976). And should it materialize, any injury therefrom would be traceable to the "decisions of independent actors," *i.e.* state or local authorities, *not* FDA's issuance of the Pfizer EUA. *Clapper*, 568 U.S. at 414; *see Children's Health Def.*, 2021 WL 5756085, at *5 (no standing to challenge FDA's issuance of Pfizer EUA because "[t]he vaccine mandates, and the potential consequences for refusing those mandates, are not fairly traceable to the specific actions of the FDA"); *Null v. FDA*, No. CV 09-1924 (RBW), 2009 WL 10744069, at *3 (D.D.C. Nov. 10, 2009). The Pfizer EUA, again, compels no action whatsoever from any parent or child.

Otherwise, Else and Dietrich object to "advertisements and societal pressures encouraging their children to receive" the Pfizer EUA vaccine. Compl. ¶ 184; *see id.* ¶¶ 3, 185–86. But "the purported indignity of receiving a" message with which one disagrees is "a psychic injury [that] falls well short of a concrete harm needed to establish Article III standing." *Glennborough Homeowners Ass'n v. U.S. Postal Serv.*, 21 F.4th 410, 415 (6th Cir. 2021); *see Diamond v. Charles*, 476 U.S. 54, 62 (1986) ("The presence of a disagreement, however sharp and acrimonious it may be, is insufficient by itself to meet Art. III's requirements."). Else and Dietrich also fail to allege how such pressures can plausibly override their legal right to withhold consent for their children to receive the EUA vaccine. *See Miller*, 118 S.W.3d at 766; Tex. Fam. Code Ann. § 151.001(6); Fact Sheet 5. Moreover, any injury deriving from the independently developed messages of third parties, such as schools, pediatricians, or stores, cannot be fairly traced to FDA. *See, e.g.*, *Clapper*, 568 U.S. at 414.

At bottom, Else and Dietrich have not borne "the burden of pleading . . . concrete facts showing that [FDA's] actual action has caused the substantial risk of harm." *Clapper*, 568 U.S. at 414 n.5. The fear that their children might receive the Pfizer vaccine over their objection "is not supported by any facts" and "purely speculative." *Crane v. Johnson*, 783 F.3d 244, 252 (5th Cir. 2015). Accordingly, they lack standing and "may not

litigate as suitors in the courts of the United States." *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 475–76 (1982).

2. With no injury to an identified member or to the group itself, CHD lacks standing

CHD asserts both associational standing, on behalf of its members, and organizational standing, on its own behalf. Compl. ¶ 5; *NAACP v. City of Kyle*, 626 F.3d 233, 237–38 (5th Cir. 2010). It has neither.

Associational standing requires that one of CHD's members "independently" possess Article III standing. *Ctr. for Biological Diversity v. U.S. EPA*, 937 F.3d 533, 536 (5th Cir. 2019). Among other things, CHD must "make specific allegations establishing that at least one identified member had suffered or would suffer harm." *Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009). Else is the only CHD member identified in the Complaint, and, as discussed above, she lacks standing. Thus, CHD lacks associational standing. *See, e.g.*, *City of Kyle*, 626 F.3d at 237 (rejecting "NAACP's associational-standing claim" given "no evidence in the record showing that a specific member of the NAACP" had standing).

Organizational standing requires that CHD exhibit a "concrete and demonstrable injury to [its] activities—with the consequent drain on [its] resources," not "simply a setback to [its] abstract social interests." *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982). CHD first alleges that "FDA's conduct toward children . . . caused a serious diversion of the organization's resources from its original mission in public education and protection of children to correct this critical error and try to protect the members and mission of CHD." Compl. ¶ 5; *see id.* ¶ 13. "Not every diversion of resources to counteract the defendant's conduct, however, establishes an injury in fact." *City of Kyle*, 626 F.3d at 238. Only a "diversion of resources" that "concretely and 'perceptibly impaired' [CHD's] ability to carry out its purpose" suffices for standing. *Id.* at 239 (quoting *Havens Realty*, 455 U.S. at 379).

CHD failed to "clearly allege facts" that demonstrate a perceptible impairment of its mission. *Spokeo*, 578 U.S. at 338 (cleaned up). CHD has not "identified any specific projects" it "had to put on hold or otherwise curtail in order to respond to the" Pfizer EUA. *City of Kyle*, 626 F.3d at 238. If the group intends to rely on litigation expenses, such costs are "fundamentally self-inflicted" and thus "insufficient to satisfy the injury-in-fact requirement." *Williams v. Parker*, 843 F.3d 617, 621 (5th Cir. 2016); *Ass'n for Retarded Citizens of Dall. v. Dall. Cty. Mental Health & Mental Retardation Ctr.*, 19 F.3d 241, 244 (5th Cir. 1994) ("The mere fact that an organization redirects some of its resources to litigation and legal counseling in response to actions or inactions of another party is insufficient to impart standing upon the organization."). CHD also has not explained how this litigation—ostensibly filed to protect "minor children," Compl. ¶ 1—"detract[s] or 'differ[s] from its routine [] activities,'" *City of Dall.*, 968 F.3d at 500 (quoting *City of Kyle*, 626 F.3d at 238). After all, CHD's self-described mission is the "protection of children." Compl. ¶ 5; *see Clark v. Edwards*, 468 F. Supp. 3d 725, 746–47 (M.D. La. 2020) (finding no "significant diversion of resources" when the alleged injury "seems consistent with [the organizations'] general activities and mission"). Because CHD's claim of resource diversion "is not supported by any facts," the alleged "injury is purely speculative" and does not "establish standing." *Crane*, 783 F.3d at 252.[5]

CHD also advances a procedural-injury theory, citing denial of "its right to petition, the chance at notice-and-comment, and its procedural remedies under the" APA. Compl. ¶ 5. Ignoring for the moment the underlying flaws with these allegations, *see infra* pages 16–17, a "bare procedural violation, divorced from any concrete harm," cannot "satisfy the injury-in-fact requirement of Article III," *Spokeo*, 578 U.S. at 341; *see Summers*, 555 U.S. at 496. That is, CHD still "must show an injury that is both concrete

[5] Far from a financial drain, CHD's advocacy against COVID-19 vaccines apparently has proved quite a boon. *See* Michelle R. Smith, AP, How a Kennedy built an anti-vaccine juggernaut amid COVID-19 (Dec. 15, 2021), https://bit.ly/3Dhr9qt.

and particular, as opposed to an undifferentiated interest in the proper application of the law." *Sierra Club v. Glickman*, 156 F.3d 606, 613 (5th Cir. 1998). Its supposed "inability to comment effectively or fully" on the Pfizer EUA could not, in and of itself, establish standing. *Defs. of Wildlife v. Perciasepe*, 714 F.3d 1317, 1325 (D.C. Cir. 2013); *see* Compl. ¶ 5. But the only other hint of concrete, organizational harm is the inadequate allegation of diverted resources. Thus, because CHD's "claimed procedural injury does not impact any concrete interest," it lacks standing to challenge the purported denial of its right to petition and procedural rights under the APA. *City of Hearne v. Johnson*, 929 F.3d 298, 302 (5th Cir. 2019); *see Shrimpers & Fishermen of RGV v. Tex. Comm'n on Env't Quality*, 968 F.3d 419, 425–26 (5th Cir. 2020). Ultimately, like Else and Dietrich, CHD must be dismissed for lack of standing. *Valley Forge*, 454 U.S. at 475–76.

B. Sovereign immunity bars Plaintiffs' causes of action

Even if the Court were to find that Plaintiffs have standing, "[t]o bring a claim against a sovereign," Plaintiffs also must show the "sovereign has waived its immunity from suit." *Walmart Inc. v. U.S. Dep't of Just.*, 21 F.4th 300, 307 (5th Cir. 2021). Such a waiver is "strictly construed, in terms of its scope, in favor of the sovereign." *Dep't of Army v. Blue Fox, Inc.*, 525 U.S. 255, 261 (1999). The APA, 5 U.S.C. § 702, is Plaintiffs' only potential source of a waiver. *See* Compl. ¶¶ 10, 157.[6] But the APA's waiver is not absolute.

[6] Although Plaintiffs invoke the general federal-question statute, 28 U.S.C. § 1331, and Declaratory Judgment Act, 28 U.S.C. § 2201, *see* Compl. ¶¶ 11, 207, neither waives sovereign immunity, *see, e.g.*, *Koehler v. United States*, 153 F.3d 263, 266 n.2 (5th Cir. 1998); *Gaar v. Quirk*, 86 F.3d 451, 453 (5th Cir. 1996). Plaintiffs also cite the mandamus statute, 28 U.S.C. § 1361, but plead no mandamus claim, *see* Compl. ¶ 11. Regardless, because Plaintiffs do not demand FDA "perform a ministerial duty imposed on it by law" but instead seek to require FDA to "alter its decision on the merits of their claims," they exceed "the function of mandamus" and any waiver of sovereign immunity in that statute. *Drake v. Panama Canal Comm'n*, 907 F.2d 532, 534–35 (5th Cir. 1990).

The APA does not apply when "statutes preclude judicial review" or when "agency action is committed to agency discretion by law." 5 U.S.C. § 701(a)(1)–(2); *see Webster v. Doe*, 486 U.S. 592, 599 (1988); *Stockman v. Fed. Election Comm'n*, 138 F.3d 144, 152 (5th Cir. 1998). For 5 U.S.C. § 701(a)(1), the Court examines whether "a particular statute precludes judicial review" by "its express language, . . . the structure of the statutory scheme, its objectives, its legislative history, and the nature of the administrative action involved." *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 345 (1984). If "the congressional intent to preclude judicial review is 'fairly discernible in the statutory scheme,'" *Drake*, 907 F.2d at 535 (quoting *Block*, 467 U.S. at 351), section 701(a)(1) applies. Alternatively, 5 U.S.C. § 701(a)(2) is implicated when the relevant statutory "language" and "structure" indicate "that its implementation was 'committed to agency discretion by law.'" *Webster*, 486 U.S. at 600. And sometimes, given the analytical overlap, both section 701(a)(1) and (a)(2) equally support exemption from the APA's waiver of sovereign immunity. *See Haitian Refugee Ctr., Inc. v. Baker*, 953 F.2d 1498, 1507–08 (11th Cir. 1992).

The Pfizer EUA was expressly issued "pursuant to" 21 U.S.C. § 360bbb-3. January Letter 1, 9–11. And 21 U.S.C. § 360bbb-3(i) states that "[a]ctions under the authority of this section by the Secretary . . . are committed to agency discretion." That language tracks section 701(a)(2)'s exception to APA review when "agency action is committed to agency discretion by law." Because the language of 21 U.S.C. § 360bbb-3(i) "is plain," the Court must enforce the statute "according to its terms." *Lamie v. U.S. Trustee*, 540 U.S. 526, 534 (2004) (quotations omitted). Indeed, the Sixth Circuit concluded this language means that EUAs "are exempt from review under the APA." *Ass'n of Am. Physicians & Surgeons v. FDA*, 2020 WL 5745974, at *3 (6th Cir. Sept. 24, 2020) (citing 5 U.S.C. § 701(a)(2)).

The Sixth Circuit's conclusion is bolstered by the "basic interpretive canon[]" that "a statute should be construed so that effect is given to all its provisions, so that no part

will be inoperative or superfluous, void or insignificant." *Corley v. United States*, 556 U.S. 303, 314 (2009) (cleaned up). Apart from committing actions to agency discretion, 21 U.S.C. § 360bbb-3(i) contains no other language. Thus, it functionally serves no other purpose than summoning the APA's exemption in 5 U.S.C. § 701(a). A failure to apply the exemption would impermissibly render 21 U.S.C. § 360bbb-3(i) meaningless.

Although the statute's plain meaning is dispositive, its purpose and structure confirm that FDA's issuance of the Pfizer EUA is "unreviewable" under section 701(a). *FDIC v. Bank of Coushatta*, 930 F.2d 1122, 1129 (5th Cir. 1991); *see Webster*, 486 U.S. at 600–01. The EUA statute was largely enacted as part of the Project BioShield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835, which granted FDA authority to issue EUAs to "streamlin[e] . . . the approval process of countermeasures" against chemical, biological, radiological, or nuclear agents that might be used against the United States. And agency discretion permeates the authorization process. For example, the Secretary "may" declare "that the circumstances exist justifying" an EUA, 21 U.S.C. § 360bbb-3(b)(1); "may" issue an EUA, *id.* § 360bbb-3(a)(1), (c); "may" impose conditions that are "necessary and appropriate to protect the public health," *id.* § 360bbb-3(e)(1)(B); and "may revise or revoke" an EUA, *id.* § 360bbb-3(g)(2); *see Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 171 (2016) ("the word 'may' . . . implies discretion"). Indeed, even when the statute directs the agency to establish conditions on EUA products, it includes discretionary caveats. *See* 21 U.S.C. § 360bbb-3(e)(1)(A) ("to the extent practicable given the applicable circumstances" and "such conditions . . . as the Secretary finds necessary or appropriate to protect the public health").

Thus, through the language, structure, and purpose of 21 U.S.C. § 360bbb-3, Congress's intent to preclude judicial review of FDA's decision to issue EUAs under 5 U.S.C. § 701(a)(1) is "fairly discernible." *Drake*, 907 F.2d at 535. Alternatively, because the "language and structure" of 21 U.S.C. § 360bbb-3 "fairly exudes deference to" FDA, 5 U.S.C. § 701(a)(2) "precludes judicial review of [this] decision[] under the APA."

Webster, 486 U.S. at 600–01; *see Bank of Coushatta*, 930 F.2d at 1129. Either way, the result is the same: no waiver of sovereign immunity and no subject-matter jurisdiction.

II. Even if this Court has jurisdiction, Plaintiffs' claims are implausible

Even if Plaintiffs could establish this Court's jurisdiction, their suit still should be dismissed for failure to plausibly state a claim for relief. "Rule 12(b)(6) requires dismissal whenever a plaintiff's claim is based on an invalid legal theory." *Residents Against Flooding v. Reinvestment Zone No. Seventeen*, 260 F. Supp. 3d 738, 803 (S.D. Tex. 2017); *see Neitzke*, 490 U.S. at 326–27. Dismissal also is required when the facts pleaded in the complaint do not "plausibly support each element" of the alleged cause of action. *Pena v. City of Rio Grande City*, 879 F.3d 613, 621 (5th Cir. 2018).

"To state a proper claim under the APA," Plaintiffs "must allege facts that, if true, plausibly establish that the agency action is arbitrary and capricious." *Blanchett v. DeVos*, 490 F. Supp. 3d 26, 32 (D.D.C. 2020); *see, e.g.*, *Palacios v. Dep't of Homeland Sec.*, 434 F. Supp. 3d 500, 506 (S.D. Tex. 2020). "Judicial review under that standard is deferential . . . . A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). Judicial review also is "at its most deferential" when a case involves "scientific determination[s]" and "predictions" by FDA that are "within its area of special expertise." *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council*, 462 U.S. 87, 103 (1983).

Although the Complaint advances numerous arguments, nowhere do Plaintiffs set forth a plausible APA claim. *First*, Plaintiffs contend that "FDA has based its emergency authorization authority" on 50 U.S.C. § 1622 and fault Congress for failing "to consider whether the COVID-19 emergency should continue." Compl. ¶¶ 168–71. Plaintiffs' first prong is factually wrong and the second is legally unavailing. The EUA was issued expressly under 21 U.S.C. § 360bbb-3. *See* January Letter 1, 9–10. The Secretary's public-

health emergency declaration under 21 U.S.C. § 360bbb-3, *see* 85 Fed. Reg. at 18,250–51, is distinct from a national-emergency declaration by the President under 50 U.S.C. § 1622. And whatever their dissatisfaction with Congress, "no cause of action lies to compel Congress to exercise its discretion to legislate on a purely political question." *Keener v. Cong. of U.S.*, 467 F.2d 952, 953 (5th Cir. 1972).

Second, Plaintiffs aver that "FDA denied CHD its procedural right to seek redress via citizen petition, a right conforming to the right to petition under the First Amendment." Compl. p. 50. The First Amendment's "Petition Clause protects the right of individuals to appeal to courts and other forums established by the government for resolution of legal disputes." *Borough of Duryea v. Guarnieri*, 564 U.S. 379, 387 (2011). "CHD *exercised that right* by filing a citizen petition on May 16, 2021." Compl. ¶ 176 (emphasis added); *see* Citizen Pet., ECF No. 1, at 64–83. FDA then responded, in great detail, a few months later. *See* Citizen Pet. Resp., ECF No. 1, at 84–137. Plaintiffs may not like that FDA disagreed with them, but "[t]he First Amendment does not mandate a result once such petitions are received." *City of Hearne*, 929 F.3d at 301.

Third, Plaintiffs believe that "FDA and CDC have altered the traditional definitions of 'Vaccine' and 'Vaccination' to encompass the COVID-19 biologics," supposedly "in violation of procedural due process." Compl. ¶ 180. For a procedural due-process claim, Plaintiffs "must first identify a protected life, liberty or property interest and then prove that governmental action resulted in a deprivation of that interest." *Baldwin v. Daniels*, 250 F.3d 943, 946 (5th Cir. 2001). Although "required to point to some" constitutionally protected interest, Plaintiffs do not and thus fail "to state a due process claim." *Gentilello v. Rege*, 627 F.3d 540, 545 (5th Cir. 2010).

Even if they had, deprivation of a constitutionally protected interest "is not in itself unconstitutional; what is unconstitutional is the deprivation of such an interest *without due process of law*." *Zinermon v. Burch*, 494 U.S. 113, 125 (1990). Plaintiffs allege a denial of "citizen participation or a notice-and-comment process when [FDA] labeled the

COVID-19 biologics as vaccines." Compl. ¶ 181. But as the Complaint's exhibits attest, *see* Citizen Pet. & Resp., ECF No. 1, at 64–137, FDA's petition process allows citizens to submit their views and request "administrative action," 21 C.F.R. § 10.25(a). And notice-and-comment is *not* required by the statutes governing issuance of EUAs, 21 U.S.C. § 360bbb-3(c)–(d), and approval of biological products like vaccines, 42 U.S.C. § 262(a).

As for the supposedly altered definitions, the only specific definitions cited in the Complaint are from a CDC informational webpage and The Free Dictionary online. Compl. ¶ 45. No factual allegations show FDA's responsibility for this Internet content. *See Iqbal*, 556 U.S. at 678. Moreover, neither the CDC webpage nor The Free Dictionary qualifies as a "substantive rule," with "the force of law," that triggers notice-and-comment under 5 U.S.C. § 553(b). *Pros. & Patients for Customized Care v. Shalala*, 56 F.3d 592, 595 (5th Cir. 1995); *see Lincoln v. Virgil*, 508 U.S. 182, 196 (1993).

Fourth, although Plaintiffs object to FDA's "market[ing] this emergency use only drug to children," Compl. ¶ 183, FDA does *not* itself market any EUA vaccine or any other vaccine. The agency may "establish conditions on advertisements and other promotional descriptive matter" for EUAs, 21 U.S.C. § 360bbb-3(e)(4), which it has done for the Pfizer EUA, *see* January Letter 19. Plaintiffs do not challenge these conditions. The Complaint also lacks any facts supporting "the reasonable inference that [FDA] is liable for" any COVID-19 vaccine marketing, *Iqbal*, 556 U.S. at 678, including "advertisements on television, radio shows, announcements and signage in stores," Compl. ¶ 185. Rather, it only describes independent recommendations of third parties like "[p]ediatricians," "school[s]," "stores," and a television program. *Id.* ¶¶ 185–86.

Fifth, Plaintiffs argue that FDA's consideration and explanation of several issues was inadequate. *See* Compl. ¶¶ 159–66, 187–97. But each alleged deficiency is refuted by agency documents, which establish on their face that Plaintiffs have not plausibly alleged FDA "entirely failed to consider an important aspect of the problem" or "offered an explanation for its decision that runs counter to the evidence before the

agency." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

- Plaintiffs allege FDA "failed to justify its conclusion that children ages 5–11 face an emergency" warranting the Pfizer EUA. Compl. ¶¶ 162, 194. Not so. The agency first concluded that SARS-CoV-2 "can cause a serious or life-threatening disease or condition," *i.e.* COVID-19. EUA Mem., ECF No. 1, at 185–87, 220; *see* January Letter 10. Although "the overall burden of COVID-19 is lower in children 5-11 years of age compared with adults," FDA found it still presents significant health risks. EUA Mem., ECF No. 1, at 185–86, 215–16. And "given the uncertainty of the COVID-19 pandemic and likelihood of continued SARS-CoV-2 transmission," the Pfizer vaccine "will likely have a substantial effect on COVID-19 associated morbidity and mortality in" the 5–11 age group due to the vaccine's effectiveness, the limitations of mitigation measures, and other factors. *Id.* at 216–21.

- Plaintiffs allege "FDA failed to articulate any standard for assessing an individualized, stratified risk for children between the ages of 5 and 11," and its risk assessment methodology "is still shrouded in mystery." Compl. ¶¶ 188, 190. However, "[a]gencies are not required to proceed by set standards in order to avoid a finding that their actions are arbitrary and capricious," *Hayward v. U.S. Dep't of Labor*, 536 F.3d 376, 382 (5th Cir. 2008), so FDA was not "obligat[ed] to make such a standard" in the first instance, Compl. ¶ 188. Furthermore, the agency fully explained its risk assessment methodology, including "a quantitative benefit-risk assessment" for "children 5-11 years of age" with six different scenarios. EUA Mem., ECF No. 1, at 217-19.

- Plaintiffs allege FDA "failed to address" Pfizer's "clinical trials." Compl. ¶ 193. In fact, the agency scrutinized the trials' structure and results in depth. *See* EUA Mem., ECF No. 1, at 196–211.

- Plaintiffs allege FDA "ignored adverse events that have been documented through the [Vaccine Adverse Events Reporting System] database." Compl. ¶ 196. On the contrary, FDA "queried" that database "for adverse event (AE) reports following administration of the Pfizer-BioNTech COVID-19 Vaccine," and analyzed the results. EUA Mem., ECF No. 1, at 192-93.

- Plaintiffs allege FDA "dismissed the effectiveness of alternative treatments." Compl. ¶ 197. But Plaintiffs concede these "alternative treatments" have not "been recognized," *i.e.* approved, by FDA for the prevention or treatment of COVID-19. *Id.* And only products that have been "approved, licensed, or

> cleared by FDA," on an "indication-specific" basis, qualify under 21 U.S.C. § 360bbb-3(c)(3). Citizen Pet. Resp., ECF No. 1, at 113 & n.82.

Sixth, Plaintiffs seek to introduce new arguments from a news article about purported "inadequacies regarding [Pfizer] clinical trials" and whether "mRNA COVID-19 vaccines" are "gene therapies." Compl. ¶¶ 191, 193. But the "focal point" for APA review is "the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (per curiam); *see Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985). Because the Court is "limited to evaluating the agency's contemporaneous explanation in light of the existing administrative record," *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2573 (2019), it necessarily "could not conclude that a decision by the [agency] was arbitrary and capricious in failing to identify, raise, and resolve *sua sponte* an issue never presented to" it, *Fleming v. U.S. Dep't of Agric.*, 987 F.3d 1093, 1100 (D.C. Cir. 2021); *see Delta Found., Inc. v. United States*, 303 F.3d 551, 562–63 (5th Cir. 2002) (during APA review, "disregard[ing]" arguments not previously raised "at the administrative level").

That outcome reflects the long-standing "general rule that courts should not topple over administrative decisions unless the administrative body . . . has erred against objection made at the time appropriate under its practice." *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952). This rule—"known as issue exhaustion"—"require[s] parties to give the agency an opportunity to address an issue before seeking judicial review of that question." *Carr v. Saul*, 141 S. Ct. 1352, 1358 (2021). Indeed, FDA regulations require that any challenger "who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new petition to modify the action." 21 C.F.R. § 10.45(f); *see id.* §§ 10.25, 10.30; *see also Carr*, 141 S. Ct. at 1358 ("issue-exhaustion rules" may be "creatures of . . . regulation").

Plaintiffs have not plausibly alleged that, when deciding to issue the Pfizer EUA for individuals aged 5 to 11, the issues discussed in the media article or of gene therapy

were part of the "administrative record" before the decisionmaker and should have been addressed *sua sponte*. *Dep't of Commerce*, 139 S. Ct. at 2573. Plaintiffs also eschewed the available administrative process to present these issues to the agency. Because a "federal court reviewing an agency determination will not ordinarily consider arguments that a litigant could have raised before the agency but chose not to," Plaintiffs have waived the issue. *Palm Valley Health Care, Inc. v. Azar*, 947 F.3d 321, 327–28 (5th Cir. 2020). Thus, Plaintiffs' new arguments cannot afford a basis to overturn the Pfizer EUA under the APA. *See Velez-Duenas v. Swacina*, 875 F. Supp. 2d 1372, 1379 (S.D. Fla. 2012) (dismissing, as "improper," an APA claim where the plaintiff asked the court "to consider documents that were not a part of the administrative record").[7]

Lastly, without a plausible APA claim, Plaintiffs cannot proceed solely based on the Declaratory Judgment Act. *See* Compl. ¶¶ 206–07. That Act does not "provide an independent basis for federal court review." *Offiong v. Holder*, 864 F. Supp. 2d 611, 626–27 (S.D. Tex. 2012). Rather, "the relevant cause of action must arise under some other federal law." *Gaar*, 86 F.3d at 453. No such cause of action exists here.

CONCLUSION

For the foregoing reasons, the Court should dismiss this case for lack of subject-matter jurisdiction and failure to state a claim upon which relief can be granted.

[7] Even if they were not waived, these arguments could not resuscitate the APA claim. For example, Plaintiffs summarily allege that FDA failed to meet its own standards for regulating gene therapy products, Compl. ¶ 61, but they critically do not identify any specific standard that FDA failed to apply in granting the Pfizer EUA, *see Iqbal*, 556 U.S. at 678–79 ("legal conclusions" are not presumed true).

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